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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/873,431 | 06/05/2001 | Karl Kolter | 51497 | 5147 |

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| EXAMINER | |
|---|---|
| FUBARA, BLESSING M | |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1615 | |

DATE MAILED: 03/10/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 09/873,431 | KOLTER ET AL | |
| | Examiner | Art Unit | |
| | Blessing M. Fubara | 1615 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *13 November 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-25* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-25* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

## DETAILED ACTION

Examiner acknowledges receipt of amendment filed 11/13/03. Claims 1-25 are pending.

1. Applicants' arguments with respect to claims 1-25 have been considered but are moot in view of the new ground(s) of rejection.

### *Claim Rejections - 35 USC § 112*

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

4. Claim 1 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for polyvinylpyrrolidone having a molecular weight of between 20,000 and 1,000,000, does not reasonably provide enablement for polyvinylpyrrolidone having molecular weight of between 20,000 and 10,000,000. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

In the specification, page 8, lines 41 and 42, a polyvinylpyrrolidone having a molecular weight of between 20,000 and 1,000,000 is disclosed and a polyvinylpyrrolidone having a molecular weight of between 20,000 and 10,000,000 is not disclosed. The specification enables a composition or preparation of a composition that comprises an active agent, polyvinyl acetate and polyvinylpyrrolidone having a molecular weight of between 20,000 and 1,000,000. There is no exemplification in the specification where a polyvinylpyrrolidone having the undisclosed

molecular weight range is mixed with polyvinyl acetate and active agent. It will be undue burden on the person of ordinary skill in the art to experiment the instant invention with the undisclosed polyvinylpyrrolidone. There is no evidence in the instant specification that the undisclosed polyvinylpyrrolidone would work in the instant invention.

It appears that the number 10,000,000 is a typographical error of 1,000,000. If this is the case, a correction is respectfully requested.

5. Claims 10 and 14-25 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

6. Regarding claims 14 and 15 the phrase "such as" renders the claims indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

It is respectfully suggested that the phrase "such as" be removed from the claims.

Claim 24 is vague and indefinite. The method of delaying the release of the active agent is not clear.

The "possible" in claim 10 renders the claim indefinite as the term confers degree of uncertainty. Claim 10 is interpreted as a ---process according to claim 1 wherein the production is both continuous and batch wise---.

***Claim Rejections - 35 USC § 102***

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 17-25 are rejected under 35 U.S.C. 102(b) as being anticipated by Goertz et al. (US 4,901,460).

Goertz discloses sustained release oral dosage of theophylline in the form of tablets or tablet cores or granules or suppositories and the sustained release composition comprises N-vinylpyrrolidone and vinyl acetate, lubricants and theophylline (examples 1 and 3; column 1, line 7; column 2, lines 17-31; column 4, lines 51-53). Theophylline is an active pharmaceutical ingredient and is antiasthmatic. Vitamins are also active agents in Goertz (column, line 67). Although Goertz heats the mixture from 50 °C to 180 °C, how a composition is made carries no patentable weight in a composition claim. From the above discussion, Goertz meets the limitations of the claims.

9. Claims 17-25 are rejected under 35 U.S.C. 102(b) as being anticipated by Ortega (US 4,837,032).

Ortega discloses compressed tablet comprising theophylline, polyvinylpyrrolidone, polyvinyl acetate, cellulose acetate phthalate and a mixture or stearic acid, magnesium stearate and talc (abstract; column 2, lines 56-68; column 3, lines 57-63; and column 4, lines 3-18 ). The tablet composition is wet granulated from a mixture heated to 40 °C to 50 °C (example I). Stearic acid is listed as an additive in the instant application (page 8, line 20) and the stearic acid of Ortega meets the limitation of additive recited in instant claim 25. How a composition is made carries no patentable weight in a composition claim. Thus, Ortega meets the limitations of the claims.

***Claim Rejections - 35 USC § 103***

10. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

11. Claims 1-7 and 9-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ortega (US 4,837,032).

Ortega discloses a process of wet granulating a mixture of theophylline, polyvinylpyrrolidone, polyvinyl acetate, cellulose acetate phthalate and a mixture or stearic acid, magnesium stearate and talc (abstract; column 2, lines 56-68; column 3, lines 57-63; and column 4, lines 3-18 ) at a temperature of 40 °C to 50 °C (example I). Regarding the molecular weight of the polyvinylpyrrolidone recited in instant claim 1, it is noted from the silence of Ortega on the molecular weight of the polyvinylpyrrolidone, that polyvinylpyrrolidone of any molecular weight can be used except declared by applicants to be contrary to Ortega's invention. Regarding the ratio of polyvinyl acetate to polyvinylpyrrolidone, it is within the purview of the person of ordinary skill or skill in the art to determine the relative amounts of the polyvinylpyrrolidone and polyvinyl acetate necessary for a sustained or controlled release formulation. Ortega teaches a sustained release composition comprising theophylline, polyvinyl acetate and polyvinylpyrrolidone, cellulose acetate phthalate and optionally lubricant (abstract). Ortega specifically teaches that water-soluble polymers or gel forming polymers are used in the composition and the water-soluble polymers or gel forming polymers in Ortega are polyvinylpyrrolidone and cellulose derivatives such as hydroxypropylcellulose (column 3, lines 49-53). There is no demonstration in applicants' specification that shows that the particles size of 20-700 mm confers unusual results to the active agent.

However, Ortega, while teaching wet granulation does not specifically disclose granulation by mixer granulation or fluidized bed granulation or extrusion granulation. But these forms of granulation are known processes of granulation. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to wet granulate the mixture of theophylline, polyvinylpyrrolidone, polyvinyl acetate, cellulose acetate phthalate and a mixture or stearic acid, magnesium stearate and talc according to Ortega. One having ordinary skill in the art would have been motivated to substitute one granulation process with another with the expectation of producing granules of the composition.

12. Claims 1 and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ortega (US 4,837,032) in view of Noda et al. (US 5,389,380).

Ortega discloses the granulation of a composition that comprises theophylline, polyvinylpyrrolidone, polyvinyl acetate, cellulose acetate phthalate and a mixture or stearic acid, magnesium stearate and talc. Ortega does not teach a theophylline composition that contains lactose, cellulose powder, mannitol, calcium diphosphate or starch. Nonetheless, Noda discloses a theophylline composition comprising excipients such as lactose, sucrose, sorbitol and mannitol and higher fatty acid or polyethylene glycol (column 4, lines 43-47 and column 5, lines 63-65); and Noda is relied upon for a teaching of theophylline composition that contains lactose or starch or mannitol excipient. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to prepare a composition comprising theophylline, polyvinylpyrrolidone, polyvinyl acetate, cellulose acetate phthalate and a mixture or stearic acid, magnesium stearate and talc. One having ordinary skill in the art would have been motivated to include excipients such as lactose, sucrose, sorbitol and mannitol and higher fatty acid or

polyethylene glycol in the theophylline composition with the expectation of producing a sustained release formulation.

***Double Patenting***

13. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

14. Claims 1, 4 and 6-25 rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-22 of U.S. Patent No. 6,635,279. Although the conflicting claims are not identical, they are not patentably distinct from each other because the difference between the issued patent and the instant application is that the issued patent is silent on the molecular weight of the polyvinylpyrrolidone. The silence of the issued patent indicates that polyvinylpyrrolidone spanning all molecular weight range may be applicable. Thus, it is within the purview of the person of ordinary skill in the art to ascertain the molecular weight of the polyvinylpyrrolidone that would be applicable in the instant invention.

Observation:

Claims 16 and 20, line 2, recite "from the group of...." It is respectfully suggested that a proper Markush language be employed in claims 16 and 20.

15. The specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicants' cooperation is requested in correcting any errors of which applicants may become aware in the specification.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Blessing M. Fubara whose telephone number is (571) 242-0594. The examiner can normally be reached on 7 a.m. to 3:30 p.m. (Monday to Friday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Blessing Fubara
Patent Examiner
Tech. Center 1600